K134045

APR 2 5 2014

Zimmer Dental
1900 Aston Avenue
Carlsbad, CA 92008
760.929.4300 (ph)
760.431.7811 (fax)

# Traditional 510(k)
# PRE-MARKET NOTIFICATION 510(k)

## 510(k) SUMMARY (21CFR807.92(a))

1. Submitter's Information:

| | |
|---|---|
| Name: | Zimmer Dental Inc. |
| Address: | 1900 Aston Ave.<br>Carlsbad, CA 92008 |
| Phone: | 760-929-4300 |
| Contact: | |
| Date Prepared: | April 23, 2014 |

2. Device Name:

| | |
|---|---|
| Trade Name: | Zimmer Zfx Titanium Abutmentfor NobelActive Implant System |
| Regulation Number: | 872.3630 |
| Classification Code: | NHA |
| Device Classification Name: | Endosseous Dental Implant Abutment |

3. Predicate Device(s):

Predicate Device No. 1

| | |
|---|---|
| Trade Name: | Zimmer Zfx Abutment for NobelReplace Implant System |
| 510(k) Number: | K120873 |
| Regulation Number: | 872.3630 |
| Classification Code: | NHA |
| Device Classification Name: | Endosseous Dental Implant Abutment |

Predicate Device No. 2

| | |
|---|---|
| Trade Name: | NobelProcera Ti Abutment |
| 510(k) Number: | K091756 |
| Regulation Number: | 872.3630 |
| Classification Code: | NHA |
| Device Classification Name: | Endosseous Dental Implant Abutment |

Predicate Device No. 3

| | |
|---|---|
| Trade Name : | Nobel Active Internal Connection Implant |
| 510(k) Number: | K071370 |
| Regulation Number : | 872.3640 |
| Classification Code : | DZE |
| Device Classification Name : | Implant, Endosseous, Root-Form |

4. Device Description:

The Zimmer Zfx Titanium Abutment for the NobelActive Implant system is designed for use with NobelActive and NobelReplace Conical Connection endosseous dental implants to support single or multi tooth restorations. The abutment/implant interface is an internal conical connection with a hexagonal interlock.

The Zimmer Zfx Titanium Abutment for NobelActive Implant System is a patient specific dental implant abutment with a competitor compatible interface. The purpose of a Patient-Specific abutment is to satisfy customer needs that are otherwise difficult to meet with off-the-shelf abutments. They can be manufactured in multiple sizes, shapes, and angles within the limits established in this submission. They frequently incorporate the modifications typically done at a dental laboratory or "chair-side" by a dentist. Traditional methodologies require the customer (dentist/laboratory technician) to begin with a "stock" abutment and use manual subtractive techniques to remove material from this original "stock" design. However, a Patient-Specific abutment will incorporate these same modifications desired by the customer (dentist/laboratory technician) at the time of fabrication at the manufacturing facility.

The engineering drawings list ranges in areas (attributes) of the abutment that may be modified depending upon patient-specific needs.

The abutment is composed of Titanium alloy (Ti6Al4V), and is secured to the implant with a separate Titanium alloy screw for retention.

The new abutments will all be available with a choice of 3.5mm and 3.9mm implant platform diameters.

5. Indications for Use:

The Zimmer Zfx Titanium Abutment for NobelActive Implant System is designed for use as a terminal or intermediate abutment for cement retained prostheses. The abutment can be used with NobelActive and NobelReplace Conical Connection implants with a Narrow Platform (NP) Ø 3.5mm or a Regular Platform (RP) Ø 3.9mm.

6. Device Comparison:

The new abutment device is substantially equivalent to the predicate relative to material, manufacturing process and general design features. It is fabricated from Titanium alloy and utilizes an internal conical connection with hexagonal

interlocking implant/abutment interface, which is identical in size and shape (for a given platform diameter) to the predicate device. The new abutment device will be affixed to the implant by a retaining screw, the same manner as the predicate.

6. Technological Characteristics

| **Feature** | **New Device** Zimmer Zfx Titanium Abutment for NobelActive Implant System | **Predicate #1** Zimmer Zfx Abutment for NobelReplace Implant System | **Predicate #2** NobelProcera (for NobelActive implants) | **Predicate #3** Nobel Esthetic Abutment Conical Connection, NP |
|---|---|---|---|---|
| Material | Titanium 6Al-4V | Titanium 6Al-4V | Titanium 6Al-4V | Titanium 6Al-4V |
| Implant Interface | Internal Conical, Internal Hex | Internal Tri-lobe | Internal Conical, Internal Hex | Internal Conical, Internal Hex |
| Emergence | Contoured, curved | Contoured, curved | Contoured, curved | Contoured, curved |
| Margin | Pre-machined | Pre-machined | Pre-machined | Pre-machined |
| Platform Diameter | 3.5mm, 3.9mm | 3.5mm, 4.3mm, 5.0mm, 6.0mm | 3.5mm, 3.9mm | 3.5mm, 3.9mm |
| Cuff Width | 3.0mm-9mm (NP) 3.4mm-9mm (RP) | 3.5mm-12.0mm | 16mm MAX | 4.8mm |
| Minimum Height | 3.0mm MIN Cone 3.0mm-12.0mm Overall | 3.0- 11.5mm Cone 3.5-12.0mm Overall | 15mm MAX Overall | 6.5mm Cone 8.0mm, 9.5mm and 11.5mm Overall |
| Retaining Screw | New device | ZFX09000642 | Cat No. 36917 and 36918 | Cat. No. 36917 and 36918 |
| Cone Angle | 0-25° | 0-20° | 0-25° | 25° |

8. Non-Clinical Testing:

Non-clinical test data was used to support the decision of substantial equivalence. This consisted of reverse engineering, compatibility analysis and mechanical fatigue testing. The NobelActive interface was reverse engineered based on actual measurements taken from NobelActive implants, abutments and retaining screws in order to assure that the Zimmer Zfx Titanium Abutmentis compatible with NobelActive and NobelReplace Conical Connection Implant Systems. Dimensional specifications were developed for the Zimmer fabricated components based on the reverse engineering results. A tolerance analysis as well as a rotational analysis was conducted to illustrate the nature of fit between the Zimmer fabricated parts and the OEM implant. To verify the compatibility of the Zimmer device to the OEM device, fatigue testing was completed using Zimmer fabricated abutments assembled to OEM implants in accordance with the FDA guidance Class II Special Controls Guidance Document: Root-form Dental Implants and Endosseous Dental Implant Abutments. The results were

compared to fatigue testing data of the predicate #3 device. Based on the reverse engineering process, as well as verification of the final connection dimensions and tolerances, the Zimmer Zfx Titanium Abutment for NobelActive Implant System can be deemed compatible with the NobelActive and NobelReplace Conical Connection implant interface.

The Zimmer Zfx Titanium Abutment for the NobelActive Implant System will be sold non-sterile and will be sterilized by the end user. The sterilization procedures listed in the Instruction For Use were validated to provide a minimum sterility assurance level of $10^{-6}$.

Additionally, Zimmer Dental implant systems were evaluated for interactions with magnetic fields during Magnetic Resonance Imaging (MRI) in accordance with the FDA Guidance: Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment. This was done to determine that the presence of the abutment poses no additional restrictions on MRI beyond those that would otherwise occur for the patient.

9. Clinical Testing

No clinical testing was performed. Non-clinical testing was used to support the decision of safety and effectiveness.

10. Conclusion

Based on our analysis, the device is substantially equivalent to the predicate.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 25, 2014

Zimmer Dental, Incorporated
Julie Lamothe, Ph.D.
Regulatory Affairs Submissions Manager
1900 Aston Ave.
Carlsbad, CA 92008

Re: K134045
Trade/Device Name: Zimmer Zfx Abutment for NobelActive Implant System
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: March 25, 2014
Received: March 28, 2014

Dear Dr. Lamothe:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

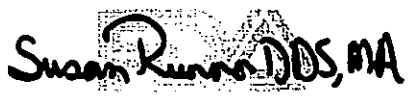
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Erin I. Keith, M.S.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Indications for Use

510(k) Number (if known): K134045

Device Name: ***Zimmer Zfx Titanium Abutment for NobelActive Implant System***

Indications For Use:

The Zimmer Zfx Titanium Abutment for NobelActive Implant System is designed for use as a terminal or intermediate abutment for cement retained prostheses. The abutment can be used with NobelActive and NobelReplace Conical Connection implants with a Narrow Platform (NP) Ø 3.5mm or Regular Platform (RP) Ø 3.9mm

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Sheena A. Green -S
2014.04.25 08:07:15 -04'00'